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10/082,221	02/26/2002	Mark W.J. Ferguson	39-257	2577

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EXAMINER

LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

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DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/082,221

Applicant(s)

FERGUSON, MARK W.J.

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/011,027.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

DETAILED ACTION

1. Formal Matters

- A. Preliminary Amendment, filed 2/26/02, has been entered into the record.
- B. Claims 1-10 are pending in the application and are the subject of this Office Action.

2. Specification

- A. The specification is objected to since it is not clear from the Experiment on page 6 from which species the IL-10 is from.

3. Claim Objections

- A. Claims 1-5, 7 and 8 are objected to since the claims are lacking commas. The claims should read as "...IL-10, or a fragment, or a partially modified form thereof, ..." Appropriate correction is required.
- B. Claims 7 and 8 are objected to. First, claim 8 should read "A method according to claim 7, wherein IL-10, or a fragment..." In addition, the word "being" in claims 7 and 8 should be replaced with the word "is." Appropriate correction is required.
- C. Claim 9 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 5. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case, claim 9 recites a method according to claim 5 for promoting the healing of wounds or fibrotic disorders with reduced scarring. The method of claim 5 is also drawn to promoting the healing of wounds or fibrotic disorders with reduced scarring.

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4. Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

A. Claims 1-4 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). For the purposes of examination of the claims, these 'use' claims will be treated as method claims.

5. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of using IL-10 to promote wound healing, does not reasonably provide enablement for methods using "a fragment or partially modified form" of IL-10. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In *In re Wands*, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

First, the breadth of the claims is excessive with regard to Applicants claiming the use of any an all fragments and partially modified forms of IL-10. Fragments and modified forms of IL-10 would contain one or more amino acid substitutions, deletions, insertions and/or additions to IL-10. Applicants have only provided guidance and working examples of the use of IL-10 to promote wound healing and have provided no guidance or working examples of fragments or modified forms of IL-10. Applicants have provided no guidance as to what critical residues are required to maintain the functional

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characteristics of IL-10 in the promotion of wound healing or for the treatment of fibrotic disorders. Furthermore, it is not predictable to one of ordinary skill in the art how to make a functional IL-10 other than that of the full-length IL-10 disclosed.

In summary, the breadth of the claims is excessive with regard to Applicants claiming any and all fragments and partially modified forms of IL-10. There is also a lack of guidance and working examples of these molecules as well as which residues are critical for protein function. These factors, along with the lack of predictability to one of ordinary skill in the art as to how to make a functional IL-10 other than that of the full-length of the disclosed IL-10, lead the Examiner to hold that undue experimentation is required to practice the invention as claimed.

6. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These are genus claims. Fragments and modified forms of IL-10 would contain one or more amino acid substitutions, deletions, insertions and/or additions to IL-10. Applicants have only provided adequate written description of the use of IL-10 to promote wound healing and have provided no written description of fragments or modified forms of IL-10. The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification and claims do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, IL-10 alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus at the time the invention was made.

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7. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 7 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 1-4 provide for the use of IL-10, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

B. Claims 1-3, 7 and 9 are confusing. It is not clear whether the IL-10 is used to promote reduced scarring, or if IL-10 is to be used to treat fibrotic disorders which have reduced scarring as compared to other fibrotic disorders.

C. Claim 5 is confusing since it recites 'A method...comprising the use.' It is suggested that the term "use" be replaced with the term "administration."

D. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The claims only recite a use, or a method of use, but do not recite how the method is to be practiced. For example, there is no step discussing administering the IL-10 composition.

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8. Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

A. Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,387,364. Although the conflicting claims are not identical, they are not patentably distinct from each other because The claims of the patent recite methods for promoting wound healing with reduced scarring, as well as treating fibrotic disorders, by administering IL-10 to a person in need of such treatment. The present application recites identical methods except that the claims do not recite "to a subject in need." However, it would have been obvious at the time of the present invention to have administered IL-10 to a person in need of treatment as opposed to a person not in need since this would be a waste of resources and could be potentially dangerous.

9. Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

A. Claims 1-3, 5, 6, 9 and 10 are rejected under 35 U.S.C. 102(a) as being anticipated by Gordon et al. (WO 93/19770). The claims are directed to the use of IL-10 in conjunction with a composition in promoting the healing of wounds or fibrotic disorders with reduced scarring. Gordon et al. teach a composition comprising IL-10 which promotes wound healing (Abstract; page 10, line 1 to page 11, line

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22; especially page 11, lines 14-17; Example 5; page 29, lines 6-12). Gordon et al. also teach a pharmaceutically acceptable carrier (page 12, line 11 to page 13, line 5). A pharmaceutically acceptable carrier is also inherent to the method described in Example 5, lines 19-23. The Gordon et al. reference meets the limitations of claims 1-3 and 5-10 since the claims are directed to a method of using IL-10 and a composition comprising IL-10 and do not limit the method to IL-10 only. Claims 4, 7, 8 and 10 are objected to since they depend from rejected base claims.

B. Claims 1-3, 5, 6, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Ferguson et al (WO 93/19769). The claims are directed to the use of a modified form of IL-10 in conjunction with a composition in promoting the healing of wounds or fibrotic disorders with reduced scarring. Since the specification does not define a "partially modified form" of IL-10, the claims are anticipated by Ferguson et al. since Ferguson et al. teach the use of non-fibrotic growth factors in combination with a pharmaceutically carrier (page 2, last paragraph). Though the Ferguson et al. reference does not specifically teach that the growth factors of the invention, including TNF, PDGF, TGF β -1, TGF β -2 and TGF β -3 are homologous to IL-10, and, therefore, partially modified forms of IL-10, it is inherent that this is the case. Callard and Gearing (The Cytokine Facts Book, 1994) do show that these compounds are all cytokines (Table 1.1, page 3) and that they share sequence homology. For example, the amino acid sequences of IL-10 (page 85) as taught by the present invention and of TGF β -1 (page 236) both share the amino acid Asn in position 53. The Callard and Gearing reference is not to be considered prior art in making this 35 USC 102(b) rejection, but only to show that the Ferguson et al. reference (WO 93/19769) does meet the limitation of "partially modified form" of IL-10.

Therefore, the cytokines listed on page 2 (first full paragraph) are partially modified forms of IL-10. Ferguson et al. also teach a method of treating a host suffering from a wound, or a fibrotic condition (Abstract; the Experiment described on page 8-18). Claims 4, 7, 8 and 10 are objected to since they depend from rejected base claims. The process steps of administering IL-10 are the same regardless of the purpose (Ex parte Novitski, 26 USPQ 1391). The instant process claims would inherently possess the wound healing activity.

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C. Claims 1-3, 5, 6, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Schwartz et al (WO 92/11861). The claims are directed to the use of a modified form of IL-10 in conjunction with a composition in promoting the healing of wounds or fibrotic disorders with reduced scarring. Though the specification does not define a "partially modified form" of IL-10, the claims are anticipated by Schwartz et al. since Schwartz et al. teach a method of using IL-4 in combination with a pharmaceutically carrier (Abstract; Experiment 7). It is inherent that IL-4 meets the limitation of a partially modified forms of IL-10.

Callard and Gearing (The Cytokine Facts Book, 1994) do show that both IL-4 and IL-10 belong to the haematopoietin family of cytokines (Table 1.1, page 3) and that they share greater than 50% sequence homology (page 18, first paragraph). The Callard and Gearing reference is not to be considered prior art in making this 35 USC 102(b) rejection, but only to show that the Schwartz et al (WO 92/11861) does meet the limitation of "partially modified form" of IL-10. Schwartz et al. also teach a method of treating a host suffering from a wound (Abstract; Experiment 7). Claims 4, 7, 8 and 10 are objected to since they depend from rejected base claims. The process steps of administering IL-10 are the same regardless of the purpose (Ex parte Novitski, 26 USPQ 1391). The instant process claims would inherently possess the wound healing activity.

D. Claims 1-3, 5, 6, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Ferguson et al. (U.S. Patent 5,972,335). The limitations of the claims are recited above. Ferguson teach treating wound healing by using a composition comprising IL-10 (column 2, lines 30-33). The process steps of administering IL-10 are the same regardless of the purpose (Ex parte Novitski, 26 USPQ 1391). The instant process claims would inherently possess the wound healing activity.

E. Claims 1-3, 5, 6, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Strom et al. (U.S. Patent 6,403,077). The limitations of the claims are recited above. Strom teach pharmaceutical compositions comprising IL-10 (column 4, lines 1-38). The process steps of administering IL-10 are the same regardless of the purpose (Ex parte Novitski, 26 USPQ 1391). The instant process claims would inherently possess the wound healing activity.

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10. Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

A. Claims 4 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon et al. (WO 93/19770). These claims are also rejected over Ferguson et al. (WO/93/19769). In addition, they are rejected over Schwartz et al. (WO/92/11861). Claims 4 and 10 teach a method of promoting the healing of chronic wounds. All of these references teach a method of promoting the healing of wounds. However, none of these references teach a method of promoting the healing of chronic wounds. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the methods of the references in this 35 USC 103(a) rejection to treat chronic wounds since chronic wounds fall into the category of wounds. One of ordinary skill in the art would have been motivated to use the methods of the references in this 35 USC 103(a) rejection to promote the healing of chronic wounds since it was well-known at the time of the present invention that IL-10, or partially modified forms thereof, could be used in the treatment of wounds. The references do not teach away from chronic wounds and, therefore, all of the references in this rejection would encompass using the method to treat chronic wounds.

B. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon et al. (WO 93/19770). These claims are also rejected over Ferguson et al. (WO/93/19769). In addition, they are rejected over Schwartz et al. (WO/92/11861). The claims are directed to the use of 1 μ M – 10 μ M IL-10 in conjunction with a composition in promoting the healing of wounds or fibrotic disorders with reduced scarring. Gordon et al., Ferguson et al. and Schwartz et al. teach a compositions comprising IL-10, or modified forms thereof which promotes wound healing with reduced scarring as states in the above 35 USC 102(b) rejections.

None of these references specifically teach a method of using IL-10 at a concentration of 1 μ M – 10 μ M. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used various concentrations of IL-10 to determine a dose-response relationship between IL-10 concentration and biological response. One of ordinary skill in the art would have been motivated

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to have determined a dose-response relationship using IL-10 in order to determine the effective concentration of IL-10 to use for a given experiment. There would have been a reasonable expectation of success for a person of ordinary skill in the art to have performed a dose-response study since these methods have long been a part of sound scientific methodology and then to have used this information in the healing of wounds or fibrotic disorders.

10. Conclusion

A. No claim is allowable.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
October 02, 2003



ROBERT LANDSMAN
PATENT EXAMINER